REMARKS

This paper is being submitted in response to the non-final Office Action dated May 4, 2007. Claim 1-28 are currently pending with claims 28-31 having been previously withdrawn.

Claim Objections:

The Examiner has objected to claim 1 because of an incorrect abbreviation for the unit of measurement "MPa". Applicants have amended the claim to correct the typographical error.

Claim Amendments:

Applicants have amended claims 1-4 and 19 to correct typographical errors and to overcome the Examiners rejections. Amended claim 1 recites a biocompatible meniscal repair device. The device comprises a biocompatible tissue repair scaffold adapted to be placed in contact with a defect in a meniscus. The scaffold comprises a nonwoven polymeric material, and has an initial modulus of elasticity greater than about 1.5 MPa and an initial suture pull-out strength greater than about 6 N. Amended claim 1 furthermore recites viable tissue disposed on the tissue repair scaffold, the viable tissue having viable cells capable of integrating with the native tissue adjacent to the tissue repair scaffold. Support for these amendments can be found in the specification, especially in paragraphs 12, and 64-68 of the published application, Publication No.: US 2005/0232967. In addition, claim 19 has also been amended to recite a scaffold having viable tissue. The viable tissue having viable cells capable of integrating with native tissue adjacent to the tissue repair scaffold.

Applicants have also cancelled claims 9, 15 and 28 without prejudice, since the limitations of claims 9 and 15 are now incorporated into amended claim 1, while the limitations of claim 28 are incorporated into amended claim 19. Applicants also add new claims 32, 33 and 34 which depend on amended claims 1 and 19. Claims 32 and 33 recite a repair device of claims 1 and 19 respectively, wherein viable tissue disposed on the tissue repair scaffold and is selected from the group consisting of minced tissue, sliced tissue, or a tissue strip. Support for the limitation of new claims 32 and 33 can be found in paragraph 65 of the published application. New claim 34 recites a repair device of claim 1, wherein the scaffold essentially consists of a high density dry laid non-woven polymeric material. Support for the limitation of new claim 34

can be found in the abstract as well as in paragraphs 8, 46 and 47 of the published application, Publication No.: 20050232967. No new subject matter has been added.

Rejection under 35 U.S.C. §112-First paragraph:

Enablement:

The Examiner has rejected claims 1-28 under 35 U.S.C. §112 first paragraph for failing to enable a person of ordinary skill in the art, to make or use the claimed repair device. Applicants respectfully disagree.

According to the Examiner, the claims are drawn to a meniscal repair device comprising a biocompatible tissue repair scaffold made of high density dry laid nonwoven polymeric material and having certain physical properties. However, due to the biodegradable nature of the polymer the claimed physical properties change as a function of time. Thus, according to the Examiner the claimed invention is not enabled.

Applicants have amended claims 1-4 and 19 to recite a biocompatible tissue repair scaffold of nonwoven polymeric material, having an *initial* modulus of elasticity greater than about 1.5 MPa and an *initial* suture pull-out strength greater than about 6 N. This amendment overcomes the Examiner's rejection that the claims can only be examined based on physical properties that are not affected by biodegradation.

As such, the instant specification discloses a range of values for the modulus of elasticity as well as for the suture retention strength of the claimed scaffolds (see paragraphs 11, 43 and 62). The examples and figures further support the amendments while enabling the claimed invention. Example 1 in the specification discloses the results from experiments aimed at comparing the suture retention properties and stiffness (elasticity) of conventional scaffolds to the scaffolds according of the present invention. In one series of experiments, a scaffold having a PDS nonwoven component at a density of 60 mg/cc and a thickness of 1 mm was mated to a 65/35 PGA/PCL foam. The scaffold was compared to a conventional knit and foam implant. In two other series of experiments, eight (8) scaffolds having different compositions and densities were prepared according to the claimed invention and their physical properties were compared to meniscal tissue as well as three conventional scaffolds. In all three experimental series the

nonwoven scaffolds (with or without foam) of the instant invention have higher suture pull out strength than the conventional scaffolds. Similar results were obtained for the stiffness test. The results are shown as bar graphs in Figures 7 and 8. Since tearing out of sutures from the scaffold matrix presents a serious problem during repair surgery, scaffolds with high suture-pullout strength values are desirable and have an advantage over scaffolds possessing lower suture pullout strength values.

The Examiner also states that the instant specification fails to provide guidance regarding the ratio or concentration of components within the polymer as well as guidance regarding the manufacture or use of a scaffold having bioactive substances (pending claims 13 and 14). As mentioned above, Example 1 discloses the mole ratio and densities of nonwoven-foam scaffolds prepared in accordance with the present invention. Paragraphs 54-61 also disclose scaffolds having different compositions and densities and prepared in accordance with the claimed invention. Furthermore, the instant specification discloses that bioactive substances can be applied to the scaffold or incorporated within the claimed scaffolds (see paragraphs 68 and 69). As such the bioactive materials can be added or incorporated within the scaffold either before, during or after manufacture of the scaffold. Alternatively, the instant specification discloses that the bioactive materials could be added before, during or after the surgical placement of the scaffold (see para 80-82 as well as Example 4) at the repair site. Thus the claimed invention is sufficiently enabled by the specification, examples and figures, and Applicants respectfully request the examiner to withdraw the rejection.

Written Description:

The Examiner has rejected claims 1-28 under 35 U.S.C. §112 first paragraph for failing to comply with the written description requirement. According to the Examiner, the claims are drawn to a genus, i.e., biocompatible scaffolds comprising nonwoven polymeric material, and the genus is not sufficiently described. Applicants respectfully disagree with the Examiner.

The Examiner once again alludes to the graph in Figures 6A and 6B as disclosing a scaffold whose physical properties vary due to biodegradation of the polymer. As mentioned above, Applicants have amended claims 1 and 19 to recite scaffolds having an *initial* suture

retention of greater than about 6 N and an *initial* modulus of elasticity greater than about 1.5 MPa.

Furthermore, the Examiner states that the tensile strength is dependent on the concentration of the polymer in the composition, and Applicants fail to provide written description of compositions of the polymers used. Contrary to the Examiner's assertion, the instant specification as well as the examples and figures provide the necessary written description to satisfy the §112 requirements. Specifically Example 1 and paragraphs 54-61 disclose scaffolds having different compositions and densities that have been prepared in accordance with the claimed invention, and have the claimed properties.

Applicants, therefore respectfully request the Examiner to withdraw this rejection.

Rejection under 35 U.S.C. §102:

Claims 1-8, 10-15, 17 and 18 are rejected under 35 U.S.C. §102 (b) as being anticipated by Bowman et. al., (U.S. Patent Publication No.: 2002/0127265), as exemplified by Boland et. al., (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243). Claim 15 has been cancelled rendering the rejection to this claim moot. Applicants respectfully disagree with the Examiner. Bowman does not anticipate each and every element of amended claim 1.

Claim 1 has been amended to recite meniscal repair implants comprising a biocompatible scaffold made of *high density dry laid nonwoven polymeric* material. The scaffold has certain physical properties such as an *initial* suture strength of greater than about 6 N and an *initial* modulus of elasticity greater than about 1.5 MPa. Furthermore, viable tissue is disposed onto the scaffold, and has cells that are capable of integrating with the adjacent native tissue.

The claimed scaffold may have significant advantageous to those of the prior art generally, and specifically to the scaffolds disclosed in Bowman et. al. As disclosed in the specification (see paragraph 62), scaffolds having improved suture retention and modulus of elasticity are better suited to handle the demanding conditions (stress and strain forces) within a knee joint. Additionally, such an implant could be better fixed within the joint, thus lowering the risk of the implant being damaged (by tearing) during fixation or migrating away from the repair site post fixation.

Additionally, the association of viable tissue with the scaffold is advantageous, because such tissue can directly provide the cells and biological factors which are required for effective tissue regeneration and for encouraging healing and tissue remodeling.

Bowman does not teach such a scaffold. The claimed meniscal repair device distinguishes over Bowman in at least the following ways:

First, Bowman does not disclose associating its scaffolds with viable tissue. Bowman teaches the use of cells to seed its scaffolds (see Bowman, paragraph 47). In fact, Example 6 of Bowman specifically discloses the isolation and culturing of chondrocytes and the seeding of scaffolds with the cultured cells. Bowman, therefore does not anticipate the elements of amended claim 1.

Second, Bowman discloses an implant that consists of one or more *layers of polymeric foam* having an open pore architecture and incorporating a reinforcing component within the *foam*. Bowman discloses that the reinforcing component can be made of bioabsorbable materials that can have a braided, knitted or nonwoven structure.

Applicants invention however, is drawn to a scaffold comprising a *high density dry laid* nonwoven polymeric material having certain beneficial properties. As mentioned above, Bowman does not disclose such an implant. Furthermore, Bowman makes *no mention* of the use of a high density dry laid nonwoven polymer as required by amended claim 1.

To anticipate a claim the cited reference must disclose each and every element of the claim. Amended claim 1, therefore distinguishes over Bowman and is patentable.

Claims 2-8, 10-14, 17 and 18 depend on patentably distinct amended claim 1. Claims 2-4 have been further amended to recite the repair device of claim 1, wherein the tissue repair scaffold has certain *initial* physical properties. The dependent claims, incorporate all the limitations of amended claim 1. These claims are therefore patentable for at least the same reasons mentioned above for amended claim 1.

Additionally, new claim 32 recites the repair device of claim 1, wherein the viable tissue disposed on the tissue repair scaffold is selected from the group consisting of minced tissue,

sliced tissue or a strip of viable tissue. As mentioned above, Bowman does not disclose or suggest associating the scaffold with viable tissue, let alone minced, sliced or a strip of tissue. Furthermore, new claim 34 requires that the repair device of claim 1 has a scaffold consisting essentially of a high density nonwoven dry laid polymeric material. None of the cited references disclose or suggest such a scaffold generally, and in particular none of the references disclose or suggest such a scaffold in combination with *viable tissue* disposed on the scaffold.

Applicants state that amended claim 1 as well as claims 2-8, 10-14, 17 and 18 which depend therefrom distinguish over Bowman and respectfully request the Examiner to withdraw the rejection.

Rejection under 35 U.S.C. §103:

Claims 1-28 are rejected under 35 U.S.C. §103 (a) as being obvious over Bowman et. al., (U.S. Patent Publication No.: 2002/0127265), as exemplified by Boland et. al., (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243), in view of Huckel et. al., (WO 01/85226). Claim 15 has been cancelled rendering the rejection to this claim moot. Applicants respectfully disagree with the Examiner regarding the remaining claims.

Huckel teaches new methods for obtaining tissue grafts. Particularly, Huckel teaches placing a biocompatible scaffold within a mammal and using it as a *template* so that cells from the tissue in contact or adjacent to the scaffold can infiltrate the scaffold. The cell seeded scaffold is then removed and used as a repair device by surgically implanting it at a selected site within the subject. It is evident from the specification of the Huckel reference that Huckel does not teach a repair device wherein *viable tissue* is *disposed on* a nonwoven biocompatible scaffold *adapted* to be placed at a defect site.

Amended claim 1 requires viable tissue to be *disposed on* the claimed nonwoven scaffold, and it further requires the *cells from the disposed tissue to be capable of integrating with native tissue adjacent to the repair scaffold.* This is at odds to the teaching of Huckel, wherein the *cells from adjacent tissue within the mammal seed the scaffold.*

As mentioned above, Bowman also does not disclose the claimed repair device. In fact, Bowman teaches a different scaffold in which a reinforcing component which may be nonwoven in structure is placed within a predominantly *porous foam scaffold.*

Applicants invention disclose a nonwoven scaffold formed by a dry lay process using polymeric fibers. Specifically, the instant specification discloses processing continuous filament yarn into crimped yarn, which is then cut into fiber of uniform length to produce the nonwoven scaffold (see paragraph 10 of the published application). Bowman does not disclose or suggest such scaffolds. Bowman discloses a scaffold made predominantly from a polymeric foam and reinforced with a mesh. Additionally, Huckel does not remedy the deficiencies of Bowman, and combining these two references would still fail to result in the claimed meniscal repair implant.

Amended claim 1 is not obvious in view of the combination of references. Claims 2-8, 10-14, 16-18 and new claims 32 and 34 depend on amended claim 1 and thus incorporate all its limitations. The dependent claims are therefore patentable over the combination of Huckel and Bowman for at least the same reasons mentioned above for amended claim 1.

Claim 19, has also been amended to recite a biocompatible meniscal repair device, comprising a biocompatible tissue repair scaffold. The scaffold is adapted to be placed in contact with a defect in a meniscus and includes a high-density, dry laid nonwoven polymeric material, a biocompatible foam, and viable tissue. Furthermore, amended claim 19 requires the tissue to be disposed on the tissue repair scaffold and contain viable cells capable of integrating with native tissue adjacent to the tissue repair scaffold.

The same reasons mentioned above in overcoming the obviousness rejection for claim 1 also apply here. As such Huckel discloses scaffolds made of porous foams that can include nonwoven material and implanting such a scaffold in a mammal so as to seed it with cells from the adjacent tissue. In contrast, amended claim 19 requires disposing viable tissue on to a high density dry laid *nonwoven* scaffold *adapted for implantation* at the site of repair. Bowman also does not teach the claimed implant and Huckel does not add to the teachings of Bowman. Thus, even if the two references were combined, the combined teachings would still fail to render obvious amended claim 19.

Furthermore, claims 20-27 and new claim 33 depend on amended claim 19 and thus incorporate all its limitations. The dependent claims are therefore patentable over the combination of Huckel and Bowman for at least the same reasons mentioned above for amended claim 19. New claim 33 is also patentable over the combination of Huckel and Bowman as neither reference discloses that the disposed viable tissue is at least one of minced, sliced or a strip of tissue.

Conclusion

In conclusion, Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

By_____

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